UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. RENÉE MARIE BUMB** **CIVIL NO. 19-2875 (RMB)**
THIS DOCUMENT RELATES TO ALL CASES	

TPP TRIAL PLAINTIFFS' BRIEF REGARDING *IN RE RHONE-POULENC RHORER* AND JURY INSTRUCTIONS

SLACK DAVIS SANGER, LLP
6001 Bold Ruler Way, Suite 100
Austin, TX 78746
Tel.: 512-795-8686
Fax: 512-795-8787
jdavis@slackdavis.com

HONIK LLC
1515 Market St., Suite 1100
Philadelphia, PA 19102
Tel.: 267-435-1300
ruben@honiklaw.com

On the Brief:
John R. Davis, Esq.
Ruben Honik, Esq.

The TPP Trial Defendants' Brief (Dkt. No. 2817) is laced with hypothetical, uncited, and imaginary state law conflicts. Defendants fail (yet again) to take into account the facts and law of *this* case (*e.g.*, disputing manifestation of the defect when Defendants admit *all* of their VCDs were contaminated and after the Court granted Plaintiffs' MIL 14), and is principally premised on an entirely distinguishable thirty year old Seventh Circuit case, *In re Rhone-Poulenc Rorer, Inc.,* 51 F.3d 1293 (7th Cir. 1995) (*"Rhone-Poulenc"*), and related argument that was already twice presented to and twice rejected by Judge Kugler in granting class certification and in denying class decertification.[1] Defendants' efforts at interlocutory Rule 23(f) appeal (in which Defendants for a third time raised the *Rhone-Poulenc* case[2]) were likewise rejected by the Third Circuit.

First, *In re Rhone-Poulenc*, the underlying authority for Defendants' arguments, is entirely distinguishable.[3] That case involved a district judge's certification of a *nationwide personal injury* class to try *novel* "serendipity"

[1] Defendants neglected to mention this at the July CMC. (*See* 7/23/24 CMC Tr., at 303:12-305:20.)

[2] Case No. 23-8005, Dkt. No. 54-2, at 5 (3d Cir. filed March 30, 2023); Dkt. No. 60 (3d Cir. Order denying Rule 23(f) petition dated May 1, 2023).

[3] Plaintiffs do not address herein Defendants' 7th Amendment reexamination argument, also citing *Rhone-Poulenc*, but note it has been roundly criticized. *See, e.g., In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Pracs. & Prod. Liab. Litig.*, No. MD 16-2695 JB/LF, 2023 WL 6121894, at *92 (D.N.M. Sept. 19, 2023).

negligence theories[4] against the defendant under *general theories of common law*, explicitly *without regard to the actual laws of the jurisdictions* and based simply on the "*assumption*" they were all similar. *Id.* at 1300. Here, by contrast, Plaintiffs have recognized that there are differences in state laws warranting the creation of subclass groupings of states with substantially similar laws with respect to the factual and legal issues present (and not present) in this case. Judge Kugler exhaustively reviewed every state's assignment within those groupings in his order granting class certification. (*See* Dkt. No. 2261, 21-23, 40, and Exhibits (Judge Kugler marking up Defendants' state-by-state claim-by-claim analyses).) As discussed *supra*, Judge Kugler was twice presented with[5] and twice rejected this very *Rhone-Poulenc* case and associated argument, dismissing it as "but a lamentation in the wind." (Decert. Op., at 8 (Dkt. No. 2657); Class Cert. Op., at 21-23, 40 (Dkt. No. 2261) ("[T[he Court has researched the correctness of the state law standards that plaintiffs advance and upon which plaintiffs base their TPPEcoLoss subclasses. The Court views its 'legal cite-checking' initiative as a key pathway to confirm that predominance has been deconstructed properly, leaving only those TPPEcoLoss subclasses that have

[4] The *Rhone-Poulenc* case involved the contamination of the blood supply at the dawn of the HIV/AIDS epidemic when the virus's existence itself was unknown. The plaintiffs presented a so-called "serendipity" theory that defendants generally were not proceeding with due care. *Id.* at 1300-01. Twelve out of thirteen juries had found the defendants not liable under this novel theory in individual trials.

[5] (*See* Dkt. No. 2008, at 22, 66 (raising *Rhone-Poulenc* opposing class certification); Dkt. No. 2637-1 (again raising *Rhone-Poulenc* in decertification motion).)

substantially similar fact and law issues that dominate throughout.").)

Second, Defendants recognize that states' model jury instructions are expressly permissive,[6] and in particular are not binding on federal judges sitting in diversity. (Dkt. No. 2817, at 2.) As long as the Court's instruction accurately conveys the law of each jurisdiction, it is of zero import whether that instruction be given one or twenty times (the former approach, of course, is vastly more efficient and will not needlessly confuse the jury). Plaintiffs' previously-submitted proposed jury instructions (Dkt. Nos. 2683-84), which are to be modified in light of intervening events including but not limited to the Court's summary judgment opinion (Dkt. No. 2694), contain more than adequate justification for the instructions given.

Third, Defendants vaguely refer to state law "nuances" but these are red herrings. (Dkt. No. 2817, at 3-5.) Defendants reference certain state express warranty laws (Florida, New York, Texas) as requiring a manifestation of the defect, without any citation. However, Judge Kugler tersely rejected this proposition at the class certification stage. (Dkt. No. 2261-1, at F-21 (rejecting Defendants' manifestation of defect authorities stating "[t]his is NOT the situation here" (emphasis in original)).) And indeed, Defendants themselves as recently as the July CMC represented to the Court in regards to Plaintiffs' MIL 14 that "[w]e're not arguing

[6] Defendants assert that Michigan's instructions are binding on *state* court judges. (Dkt. No. 2817, at 2.) No Michigan claims are subject to this trial, however.

that [the pills] don't contain nitrosamines[.]" (7/23/24 Tr., at 230:19-20.) The Court granted Plaintiffs' MIL 14 upon this representation, and so Defendants are precluded at trial from contesting manifestation of the defect. (Id., at 231:3-4 ("So they're not going to say that.").)

Again without citation, Defendants assert certain state express warranty laws require proof that the statement formed a "basis of the bargain" while others may not. (Dkt. No. 2817, at 5.) However, the Court has already endorsed Plaintiffs' "basis of the bargain" theory, both at the motion to dismiss stage and at summary judgment. (MTD Op. 3, at 14 ("The Mfrs' very naming of the drug as valsartan or valsartan-containing amounted to an express warranty on which plaintiffs had no choice but to 'rely'[.]" (Dkt. No. 775)); *see also* SJ Op., at 29 ("The Court agrees with its MTD 3 Opinion and with Ps declarations … that Ds labeling of their VCDs as valsartan constituted an express warranty.").)

Plaintiffs' classwide proof for basis-of-the-bargain was reaffirmed in Judge Kugler's summary judgment opinion. (Dkt. No. 2694, at 43 ("Contrary to Ds assertion in their Omni SJ brief, the bolded items **[FDA-approved package inserts, the product label, published data from clinical trials, and literature**] may indeed constitute Ds 'statements' upon which the TPP formulary-creating agents could and did rely.").) Defendants do not deny that they sold each of their VCDs with the FDA-

approved product labeling.[7] Plaintiffs' proposed instructions will accurately instruct regarding "basis of the bargain" as to all the express warranty relevant jurisdictions.

With respect to fraud, Defendants re-raise previously rejected arguments regarding scienter and materiality, again providing no citations. As an initial point, Plaintiffs' subclass groupings for fraud claims as modified and adopted by Judge Kugler in his class certification and class notice orders (Dkt. Nos. 2261, 2535) were explicitly designed to reflect differences in the level of scienter required. (*See* Class Cert. Op., at 40 (Dkt. No. 2261).) Plaintiffs' forthcoming proposed instructions accurately address (with authorities) both scienter and materiality.

Finally, for the CPL claims, Defendants (again, with no citations) raise issues regarding proof of: (1) effect on the public interest; (2) differing levels of scienter; and (3) consumer purpose. For the public interest element (only under Nebraska and Washington law), Plaintiffs' proposed instructions and verdict form accurately capture this requirement. And as with the fraud claims, Plaintiffs' CPL subclass groupings explicitly account for the varied standards of scienter, which were reviewed, modified, and approved by Judge Kugler. Finally, only one state (New York) has a consumer purpose requirement, on which the jury will be instructed.

Dated: August 30, 2024 Respectfully submitted,

[7] This admission combined with evidence to be introduced at trial that Defendants themselves would not have sold, retail pharmacies would not have dispensed, and TPPs would not have paid for Defendants' adulterated and contaminated VCD prescription drugs should yield a directed verdict in Plaintiffs' favor on this point.

/s/ John R. Davis
SLACK DAVIS SANGER, LLP
6001 Bold Ruler Way, Suite 100
Austin, TX 78746
Tel.: 512-795-8686
Fax: 512-795-8787
jdavis@slackdavis.com

/s/ Ruben Honik
HONIK LLC,
1515 Market St., Suite 1100
Philadelphia, PA 19102
Tel.: 267-435-1300
ruben@honiklaw.com

MDL PEC AND/OR CO-LEAD COUNSEL FOR THE PLAINTIFFS

/s/ Ruben Honik
Ruben Honik
HONIK LLC
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Phone: (267) 435-1300
ruben@honiklaw.com

/s/ Daniel Nigh
Daniel Nigh
Nigh Goldenberg Raso & Vaughn, PLLC
14 Ridge Square NW
Third Floor
Washington, D.C. 20016
Phone: (850) 600-8090
dnigh@nighgoldenberg.com

/s/ Adam Slater
Adam Slater
MAZIE, SLATER, KATZ & FREEMAN, LLC
103 Eisenhower Pkwy, 2nd Flr.
Roseland, NJ 07068
Phone: (973) 228-9898
aslater@mazieslater.com

/s/ Conlee S. Whiteley
Conlee S. Whiteley
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504)-524-5777
c.whiteley@kanner-law.com

MDL Plaintiffs' Co-Lead Counsel

/s/ *Jorge Mestre*
Jorge Mestre
RIVERO MESTRE LLP
2525 Ponce de Leon Blvd., Suite 1000
Miami, FL 33134
Phone (305) 445-2500
jmestre@riveromestre.com

/s/ *Gregory P. Hansel*
Gregory P. Hansel
PRETI, FLAHERTY, BELIVEAU & PACHIOS, CHARTERED, LLP
One City Center
P.O. Box 9546
Portland, ME 04112
Phone: (207) 791-3000
ghansel@preti.com

Third-Party Payor Economic Loss Co-Lead Class Counsel

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 30, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s John R. Davis_____